stryker® ENDOSCOPY

MAY 15 2000

K000493

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name: Laparoscope, General & Plastic Surgery Arthroscope and Accessories

Common and Usual Name: Irrigation Tube Set

Proprietary Name: Stryker Irrigation Tube Set

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker Irrigation Tube Set consists of flexible tubing, tube clamps, spikes, and an elastic connector. The tube set will be labeled sterile, non-pyrogenic, for single use only.

The tube set components contacting the patient are constructed of materials which will be tested for biocompatibility per ISO-10993 and General Program Memorandum #G95-1. Tube set sterilization will be per EN 550 (Ethylene-oxide) or EN 552 (Irradiation) with sterility validated to a minimum sterility assurance level of 10^{-6}. A class 100,000 cleanroom will be utilized to control pyrogens during assembly. The Limulus Amebocyte Lysate (LAL) test will be used to ensure device non-pyrogenicity.

The Stryker Irrigation Tube Set is equivalent in safety and efficacy to a variety of devices currently marketed including the McGaw Universal Spike Irrigation Set, the Baxter Arthroscopic Irrigation Set, and the Linvatec Gravity Irrigation Disposable Tubing Set.

The Stryker Irrigation Tube Set does not raise new issues when compared to the currently marketed predicate devices. Therefore, it is considered substantially equivalent to those devices.

Contact:

Mark Kuiper
Design Engineer
Stryker Endoscopy

Date: February 9, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2000

Mr. Mark Kuiper
Design Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K000493
Trade Name: Stryker Irrigation Tube Set
Regulatory Class: II
Product Code: GCJ
Dated: February 9, 2000
Received: February 15, 2000

Dear Mr. Kuiper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

February 9, 1999

510(k) Number if known: K000493

INDICATION FOR USE:

The Stryker Irrigation Tube Set provides sterile irrigant solution to the surgical site. The device is intended for use in general surgery, both open and minimally invasive including arthroscopy, laparoscopy, gynecology, urology, otolaryngology, and plastic surgery applications that require surgical site irrigation or distention. The tube set is intended for single use only with saline solution, Ringer's lactate or other irrigants the surgeon deems appropriate.

CONTRAINDICATION FOR USE:

The Stryker Irrigation Tube Set is contraindicated when, in the judgement of a medical practicioner, surgical site irrigation or distention would be contrary to the best interest of the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000493

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)